REMARKS

Formal Matters

Claims 4-10 and 12-14 are pending and currently under consideration. Claims 4-6, 12, and 14 are amended herein. New claims 15 and 16 have been added.

Claims 4-6 and 12 have been amended to recite, "wherein the binding takes place in the region of . . . the following four epitopes (1) to (4) of the carbohydrate deficient transferrin sequence," with claims referring to two, three, or four of the epitopes. Support for this amendment can be found in the specification on page 2, lines 2-8; page 3, lines 20-27; page 5, lines 28-35; and page 22, lines 7-10. Specifically, page 2, lines 2-8 recite, "[i]t has been found with the aid of epitope mapping experiments that antibodies of the invention, in contrast to prior art antibodies, bind simultaneously to different segments of the [carbohydrate deficient tranferrin] CDT sequence. It was inferred from this that the epitopes recognized by the antibodies of the invention are discontinuous epitopes." Thus, no new matter has been added.

Claims 5 and 6 have also been amended to no longer depend from claim 4. The amendments simply incorporate the language from claim 4 into claims 5 and 6, to render them independent claims. Support for independent claims 5 and 6 can be found on page 3 lines 29-32 of the specification, which recite, "[t]he present invention further relates to an antibody of this type whose binding takes place only in the region of only three or of only two of the aforementioned segments (1) to (4) of the sequence." Thus, no new matter has been added.

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Claim 12 has been further amended to recite "obtaining antibodies from the selected hybrid cell clone." This amendment is simply grammatical and is inherently supported by claim 12, as originally filed. Further support for the amendment can be found in Example 5, pages 9-10 of the specification, which teaches the claimed process for preparing antibodies. Thus, no new matter has been added.

Claim 14 has been amended to recite the content of the test kit. As amended, claim 14 recites that the test kit comprises "an antibody which binds selectively to carbohydrate deficient transferrin, wherein the antibody binding takes place in the region of two of . . . epitopes (1) to (4) of the carbohydrate deficient transferrin sequence." Support for this amendment can be found, *e.g.*, in Example 7 on pages 15-18 of the specification, which teaches an assay for detecting carbohydrate deficient transferrin using the antibodies of the invention. New claims 15 and 16 further limit claim 14 by reciting that the antibody binding takes place within three or four of epitopes (1) to (4). Support for these claims can be found on page 3 lines 29-32 of the specification (cited above) and in the claims as originally filed. Thus, no new matter has been added.

Finally, Applicant acknowledges with appreciation that the Office has withdrawn the objection to claims 1 and 4 for reciting "[an] antibody" and has not maintained its rejection of claims 1-3, 7, 10, 11, 13, and 14 under 35 U.S.C. § 102(b).

Claim Rejections under 35 U.S.C. § 112 ¶ 1 - Enablement

Applicant notes with appreciation that the Office has withdrawn the enablement rejections of claims 4-7, 10, and 12-14. However, the Office has maintained the

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rejection of claims 8-9 under 35 U.S.C. § 112 ¶ 1 because the Microorganism Deposit Declaration under 37 C.F.R. § 1.808(a) filed on April 14, 2006, was allegedly defective. The Office argues that because Accession Number DSM ACC2540 was stated twice, it is unclear which accession numbers correspond to which cell cultures. (Office action, page 2.) In response, Applicant herein files the attached Supplemental Microorganism Deposit Declaration under 37 C.F.R. § 1.808(a) which corrects the inadvertent error in the duplicate accession numbers. Applicant again notes that the specification discloses the date of deposit and the name and address of the depository in the paragraph spanning pages 3-4. Thus, Applicant submits that the rejection of claims 8 and 9 have been obviated by this filing and requests that the rejection be withdrawn.

Claim Rejections under 35 U.S.C. § 112 ¶ 1 - Written Description

Applicant notes with appreciation that the Office has withdrawn the written description rejections of claims 4-7, 10, and 13-14. However, the Office maintains the rejection of claim 12 because the specification allegedly lacks written description of the "process known to the skilled worker" for obtaining antibodies "from the hybrid cell clone selected this way." (Office Action, page 3.) Applicant's representative thanks Examiner Huynh for allowing a telephone conference on September 11, 2006, to clarify that the intended rejection under 35 U.S.C. § 112 ¶ 1 was for claim 12 only. Applicant respectfully traverses the rejection of claim 12.

The Office argues that "it appears claim 12 is a translation from a foreign language" and that consequently, it is not clear "which 'process' and which 'this way' known to the skilled worker . . . is/are part of the claimed invention." (Office Action,

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page 4.) As discussed above, Applicant has amended claim 12 to remove the phrase "by a process known to the skilled worker," rendering moot the Office's question as to which "process" is part of the claimed invention. In the event the Office might apply its argument that "there is insufficient written description about the process step of obtaining antibodies" (Office Action, page 3) to currently amended claim 12, Applicant respectfully submits that the specification is replete with written description support for a process of obtaining antibodies from hybridoma cells. Example 5 on pages 9-12 of the specification provides detailed written description of the claimed process for obtaining antibodies and additional support for the claimed process can be found on page 5, lines 7-38. Thus, the Office's argument that it is not clear which "process" is part of the claimed invention, does not apply to newly amended claim 12.

Applicant has also amended claim 12 to recite that the final step of the process for preparing antibodies according to the invention involves "obtaining antibodies from the selected hybrid cell clone." This language clearly states that the antibodies are obtained from the hybrid cell clone selected by the process described in claim 12. Furthermore, as discussed above, Applicant submits that the specification provides substantial written description support for the selection process described in claim 12. (*See, e.g.*, Example 5, pages 9-10.) Thus, the amendments to claim 12 obviate the Office's questions as to which "process" and which "this way" is/are part of the claimed invention. Applicant respectfully requests that the written description rejection of claim 12 be withdrawn.

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Finally, although Examiner Hyunh confirmed that the written description rejection applied to claim 12 only, Applicants have also amended claim 14 to address the Office's argument that the "content of the [test] kit is not adequately described." (Office Action, page 4.) As currently amended, claim 14 now recites the required antibody element of the test kit. Thus, Applicant submits that claim 14, as amended, meets the written description requirements set forth in 35 U.S.C. § 112 ¶ 1.

Claim Rejections under 35 U.S.C. § 112 ¶ 2 - Indefiniteness

Applicant acknowledges with appreciation that the Office has withdrawn its previous indefiniteness rejections. However, Applicant notes that the Office has made a new rejection of claims 4-10 and 12-14 under 35 U.S.C. § 112 ¶ 2 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office argues that the "particular antibody that binds to all *four* segments (1) to (4) in claims 4 and 12 is indefinite and ambiguous because the antibody in the dependent claims 5 and 6 where the binding takes place only in the region of *three* or *two* segments (1) to (4) of the carbohydrate deficient transferring sequence." (Office Action, page 4.)

Without acquiescing to the rejection, Applicant has amended claims 5 and 6 to remove their dependency from claim 4. As currently amended, independent claims 5 and 6 incorporate all of the elements of claim 4 and limit the antibody to one which binds three or two of epitopes (1) to (4), respectively. Since claims 5 and 6 are no longer drafted to further limit claim 4, Applicant submits that there is no indefiniteness regarding the antibodies of the instantly claimed invention.

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The Office also argues that claims 4-10 and 12-14 are indefinite because "the region of SEQ ID NO:1 to which the antibody binds has no common amino acids in the region of SEQ ID NO:2, SEQ ID NO:3 and/or SEQ ID NO:4." (Office Action, page 4.) Applicant respectfully traverses. The Office seems to imply that the antibody of the invention must bind to an amino acid sequence that is shared among SEQ ID NOs 1-4. However, this is not the case. As stated on page 2, lines 2-6 of the specification, "[i]t has been found with the aid of epitope-mapping experiments that antibodies of the invention, in contrast to prior art antibodies, bind simultaneously to different segments of the CDT sequence. It was inferred from this that the epitopes recognized by the antibodies of the invention are discontinuous epitopes." (Emphasis added.) It is clear that the antibody of the invention binds to different amino acid sequences in segments (1) to (4) (SEQ ID NOs 1-4). Thus, the Office's argument that there must be some common amino acids among SEQ ID NOs 1-4 is unfounded.

To make this point clear, claims 4-10 and 12-14 have been amended to recite that "binding takes place [only] in the region of [three of/two of] the following four epitopes (1) to (4) of the carbohydrate deficient transferrin sequence." This amendment removes any alleged indefiniteness due to the term "segments" and clearly identifies that the antibodies of the invention recognize discontinuous epitopes. Applicant submits that this new claim language identifies that the antibody of the claimed invention binds simultaneously to different segments of the CDT sequence and thus, SEQ ID NOs 1-4 need not share a common amino acid sequence. Accordingly, Applicant respectfully requests that the indefiniteness rejection be withdrawn.

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Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 6, 2006

By: Rebecca M. McNeill
Rebecca M. McNeill
Reg. No. 43,796

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